

Appl. Ser. No. 08/943,776  
Request for R.C.E. dated October 11, 2005

### **REMARKS/ARGUMENTS**

The listing of the claims are presented above. Claims 1, 6, 10, 13, 16, 20-21, 23-24, 27-29, and 31-43 are currently pending in the application. Claims 2-5, 7-9, 11, 12, 14, 15, 17-19, 22, 25, 26, and 30 are canceled. Claims 20 and 21 have been withdrawn from prosecution. Claims 1, 13, 16, 29, 31, 35, 37, 38 and 39 are currently amended. Claims 1, 13 and 16 are amended to incorporate claims 3, 14, and 26 respectively. Claims 35, 37, 38 and 39 are amended to more precisely recite the subject matter considered to be the invention. Claim 39 as amended above differs slightly from amended claim 39 of the Response of August 10, 2005, in that it recites --A process for preparing a protein comprising amino acids 1 through 411 of SEQ ID NO: 6, or a fragment thereof, comprising culturing a host cell containing a vector comprising the DNA of claim 33.-- Claim 39 of the Response of August 10, 2005 recites --A process for preparing a protein having an amino acid sequence comprising amino acids 1 through 411 of SEQ ID NO: 6 or a fragment thereof, comprising culturing a host cell containing a vector comprising the DNA of claim 33.--

Basis for the amendments to the claims is present in the specification and therefore no new matter is added by these amendments. Entry of the amendments to the claims, and consideration of the remarks presented herein is respectfully requested.

### **Double Patenting Objection**

Claim 40 is objected to under 37 CFR § 1.75 as being a substantial duplicate of claim 33. This rejection is respectfully traversed. Applicants respectfully point out that claim 33 recites a DNA molecule whereas claim 40 recites a polypeptide molecule. Applicants maintain that these two claims do not recite the same or substantially the same subject matter and request clarification of the objection to claim 40 on this basis.

### **Rejections under 35 U.S.C. § 112**

Applicants appreciate the withdrawal of the previous rejection of claims 3, 7, 11, 14 and 26 on the basis of 35 U.S.C. § 112, first paragraph, written description requirement.

Appl. Ser. No. 08/943,776  
Request for R.C.E. dated October 11, 2005

Claim 31, 32 and 34 are rejected on the basis of 35 U.S.C. § 112, second paragraph as indefinite. This rejection has been addressed by amending claim 31 as recommended by the Examiner, amending "fragments" to recite "a fragment". Therefore, withdrawal of the rejection of claims 31, 32 and 34 on the basis of 35 U.S.C. § 112, first paragraph is respectfully requested.

**Rejections on the Basis of 35 U.S.C. § 102(e)**

Claims 3, 7, 11, 14, 22-28, 31-32, and 39 to 43 remain rejected on the basis of 35 U.S.C. § 102(e) over Yu et al, U.S. Patent 6,153,402 ('402 patent). This rejection is respectfully traversed.

Applicants first point out that the subject matter of claim 3, 7, 11, 14, and 26 has now been written into claims 1, 6, 10, 13, and 16 respectively. In addition, to expedite prosecution of these claims, claims 1, 13, and 16 have been amended to recite proteins comprising an amino acid sequence that is at least about 99% identical to amino acids 1 through 417 of SEQ ID NO: 2.

The Examiner has stated that the Yu et al. patent '402 discloses nucleic acids and polypeptides 90% identical to the "functional protein". Applicants point out that the priority document of '402, provisional application 60/013,285 filed March 12, 1996, does not disclose SEQ ID NO: 1 or 2 of the present application or any DNA or polypeptide having greater than 97.5% identity to SEQ ID NO: 1 or 2. For purposes of expediting prosecution, Applicants have amended the claims to recite proteins comprising an amino acid sequence at least 99% identical to SEQ ID NO: 2. Therefore, since the provisional application does not disclose the "functional protein", i.e., SEQ ID NO: 2, it cannot disclose polypeptides 90% identical to the functional protein, nor polypeptides 99% identical to the protein disclosed in SEQ ID NO: 2. Applicants submit that the claims 1, 6, 10, 13, 16, 23, 24, 27, 29, 31 and 32 recite polypeptide and DNA sequences not disclosed in the March 12, 1996 priority document. Isolated polypeptides recited in claims 23 and 31, for example and DNA encoding them are not described in the '402 priority document, since these sequences are not identical to the sequences of DR3-VI. Therefore, Applicants request

Appl. Ser. No. 08/943,776  
Request for R.C.E. dated October 11, 2005

reconsideration and withdrawal of the rejection of these claim on the basis of 35 U.S.C. §102(e) as anticipated by the '402 patent.

Furthermore, Applicants point out that SEQ ID NO: 5 and 6, murine sequences, are not described in the '402 patent at al. The murine AIR polypeptide, SEQ ID NO: 6 has about 65% identity to human AIR polypeptide, SEQ ID NO: 2. Therefore, Applicant respectfully points out that all claims directed to SEQ ID NO: 5 and 6, or sequences having 70% identity to SEQ ID NO: 6, are not disclosed in the '402 patent. In particular claim 39 recites a process for making a protein comprising amino acids 1 through 411 of SEQ ID NO: 6 or a fragment thereof, and claim 43 recites an isolated polypeptide comprising an amino acid sequence that is at least 70% identical to SEQ ID NO: 6, wherein the protein is capable of inducing apoptosis. Therefore, Applicants respectfully request reconsideration and withdrawal of the 102(e) rejection of claims 39 and 43 as anticipated by the '402 patent.

Claims 1, 3, 6, 7, 10, 11, 13-14, 16 and 22-32, 39 and 43 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent 6,462,176 and US Patent Application Publication US2002/0192729A1 (Ashkenazi-1 and -2). This rejection is respectfully traversed. Applicants wishes to point out that Ashkenazi-1 and -2 also do not disclose SEQ ID NO: 5 and 6 of the present invention, nor sequences which are 70% or greater than SEQ ID NO: 6, nor polynucleotide sequence which encode SEQ ID NO: 6 or amino acid sequences 70% or more identical. Therefore, Applicants request the reconsideration and withdrawal of the rejection of claims 39 and 43 on the basis of 35 U.S.C. § 102(e) as anticipated by the Ashkenazi references.

Applicants wish to defer consideration of an interference on the remaining claims until the Examiner has considered amendments and arguments presented above on the other remaining grounds for rejection.

Appl. Ser. No. 08/943,776  
Request for R.C.E. dated October 11, 2005

**Remarks in Response to Advisory Action**

Applicants herein respond to the comments presented in the Advisory Action of Sept. 30, 2005. The Advisory Action has concluded that claims 33-38 and 40-42 are allowable, and that claims 1, 3, 6, 7, 10, 11, 13, 14, 16, 22-32, 39 and 43 are rejected.

First, Applicants request that the amendments to the claims presented above, originally presented in the Response of August 10, 2005, be entered and the remarks set forth above be considered.

Second, Applicants appreciate the removal of the objection to claim 40 on the grounds of Double Patenting.

Third, Applicants appreciate the Examiner's conclusion in the Advisory Action of Sept. 30, 2005 (statement 4) that claims 31-38 and 40-42 are allowable. Applicants request that the Examiner consider in particular claims 39 and 43 as presented above. Claims 39 and 43 relate to SEQ ID NO: 6 of the instant application. SEQ ID NO: 6 is not described in US Patent 6,153,402 to Yu et al. SEQ ID NO: 6 is the sequence of the murine AIR polypeptide having about 65% identity to the human AIR polypeptide, SEQ ID NO: 2 of the present invention. Therefore, Applicants respectfully point out that all claims directed to SEQ ID NO: 6, or sequences having 70% identity to SEQ ID NO: 6, are not disclosed in the Yu et al. patent. Applicants request that the rejection on the basis of 35 U.S.C. § 102(e) over Yu et al. be withdrawn. Applicants point out that claim 35, found allowable by the Examiner, recites DNA sequences encoding a polypeptide comprising an amino acid sequence at least 70% identical to SEQ ID NO: 6, wherein the protein is capable of inducing apoptosis. Claim 43 recites the polypeptide claim corresponding to this DNA claim.

Appl. Ser. No. 08/943,776  
Request for R.C.E. dated October 11, 2005

### CONCLUSION

Entry of the amendments to the claims and consideration of the remarks presented above is respectfully requested.

Applicants request that upon consideration of the Response and Amendment of the Claims originally filed August 10, 2005, and submitted again above, and the additional remarks submitted above, that the Examiner will reconsider the rejection of the claims, and, in particular, find pending claims 39 and 43 allowable.

Applicants' attorney invites the Examiner to call her at the number below if it would be helpful in advancing the prosecution of this application.

Immunex Corporation  
1201 Amgen Court West  
Seattle, Washington 98119-3105  
Telephone: (206) 265-8294

Respectfully submitted,



Christine M. Bellas  
Attorney for Applicant  
Registration No. 34,122

### CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below.

Signed:  Date: Oct. 11, 2005  
Nanci M. Kertson

gj111002 10/11/05